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(54) Title: INTERVENTIONAL RADIOLOGY GUIDANCE SYSTEM

(57) Abstract

A system and method for guiding interventional radiological procedures. A constantly updated 3D ultrasound data volume of the area of the body in which the procedure is being performed is obtained. 2D ultrasound images in multiple desired orientations are generated from the 3D volume and displayed. Software-based image processing of the 3D volume is performed to identify, graphically mark, and track the movements, on the 2D ultrasound images, of the surgical instrument being used, the target of the procedure and the structures which it is desired to avoid. Visual and audible signals are generated to aid the operator in optimizing the 3D orientation of the surgical instrument relative to the target, to inform the operator when the target has been reached, and to warn the operator when the surgical instrument is approaching a structure which it is desired to avoid.

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INTERVENTIONAL RADIOLOGY GUIDANCE SYSTEM

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to medical imaging technology, and, in particular, it concerns an interventional radiology guidance system and method.

It is known that needles, biopsy instruments and other surgical instruments are used in many different kinds of interventional, radiologically guided, medical procedures. For example, tissue biopsy and fine needle aspiration are two methods often used to determine the nature of a tissue within the human body, one or both of these procedures usually being performed as a first step in determining the nature of a potentially malignant growth. Fluid drainage and tissue ablation are other procedures in which a needle is used; for example, when draining fluid from around the lungs, heart, or joints, or when eradicating a growth in the liver by injecting alcohol into the growth. When performing such procedures, radiological guidance is required so as to successfully navigate the instrument to the desired organ or tissue (hereinafter referred to as the target), while avoiding other organs, tissues or the like (hereinafter referred to as "avoidance targets"). Radiological guidance is also used during intraoperative procedures.

All of these procedures are currently performed using one of several different radiological imaging modalities: two dimensional (2D) ultrasound, computerized tomography (CT), magnetic resonance imaging (MRI), or magnetic resonance therapeutics (MRT). Of these, 2D ultrasound is the most widely used guidance modality, due to its widespread availability, low cost, lack of radiation exposure, and ability to generate images in real time.

2D ultrasound, however, suffers from several limitations:

1. It is often difficult for the operator to see the instrument in the ultrasound image, as the acoustic contrast between the instrument and the surrounding tissue may be weak or variable.

2. Usually the instrument, such as a needle, cannot be perfectly oriented within and parallel to the plane of the 2D ultrasound image, because the physical presence of the ultrasound transducer of necessity displaces the surgical instrument, and vice-versa. The surgical instrument thus often passes through the plane of the ultrasound image at an angle. As such, it is difficult for the operator to be sure that the 2D ultrasound image of the end of the instrument truly represents the tip of the instrument, rather than merely the shaft of the instrument where it leaves the plane of the ultrasound image. This difficulty in identifying the tip of the instrument hinders the operator in appropriately orienting the instrument relative to the targets or avoidance targets. For similar reasons, when viewing a single 2D image, the operator cannot know with certainty that the instrument tip has entered the target, or has avoided an avoidance target.

3. It may be difficult for the operator to orient the ultrasound probe such that both the instrument and the target (or avoidance target) are visualized in a single 2D imaging plane.

4. Even if the operator can see both the instrument and the target (or avoidance target) in a single 2D image, it is difficult to determine if they are on the same 3 dimensional (3D) plane, both because of the inherent difficulty in extrapolating 3D conclusions from a single 2D image, and because the 2D ultrasound image is derived from an ultrasound beam which itself is of a certain thickness, such thickness not being depicted in the viewed 2D image. As such, it is difficult for the operator to determine the appropriate 3D angle at which to insert and advance the instrument, so that the tip will enter the target, or avoid the avoidance target.

5. It is difficult for the operator to track the target (or the avoidance target) by eye, as it often moves along with movement of the instrument.

6. If the instrument tip does enter the target, this fact cannot be graphically and definitively documented for future reference.

As CT provides better image resolution than does 2D ultrasound, it is often preferred as an imaging modality for radiological guidance of interventional procedures. CT, however, still suffers from the same 3D orientational drawbacks mentioned above with regard to 2D ultrasound. In addition, CT entails exposure to radiation and does not readily provide real time imaging. MRI and MRT are rarely used due to their prohibitive expensive and lack of availability.

An interventional radiological guidance system using mechanical, externally mounted, 6-degree-of-freedom (6 DOF) receivers to track the spatial location of sensors mounted on the external portion of the surgical instrument, and then use this spatial location data to display a graphic, on an ultrasound screen, depicting the 3D spatial location of the surgical instrument within the body, has been described by King (US patent # 5,608,849; issued March 4, 1997). This system, however, does not identify and track the targets and avoidance targets of the interventional medical procedure. Furthermore, several deficiencies in the use of mechanical sensors to identify and track a surgical instrument within a body make this system innacurate:

1. Sensor-based spatial location data needs to be accurately aligned with external and internal reference coordinates. This process of mechanical alignment is a significant source of data inaccuracy.

2. Once the spatial location data for the surgical instrument has been determined, a graphic, depicting the instrument, needs to be accurately superimposed on the appropriate pixels in the 2D ultrasound image being viewed by the operator. As this process cannot be 100% precise, a further source of inaccuracy is introduced.

3. The instrument's resiliency, that is, the degree to which its shape may bend or become deformed once inserted into a body, cannot be appreciated by externally mounted sensors. As such, this method results in the instrument being depicted as if it were completely rigid, an often invalid assumption.

Other mechanically-based tracking systems would suffer from the above deficiencies, as well additional sources of inaccuracy specific to the mechanical technology being used. For example, the influence of external magnetic fields (if a magnetic tracking system is used), or interference with line of sight (if an optical system is used).

There is therefore a need for an accurate, ultrasound based, radiological guidance system which aids the operator performing an interventional medical procedure to identify the instrument, the target, and the avoidance targets, to appropriately orient the instrument in three dimensions, and to confirm and document successful placement of the instrument relative to the target.

SUMMARY OF THE INVENTION

The present invention is a software based method and system for graphically marking the targets and avoidance targets of an interventional procedure, for tracking their movements and the movements of the instrument being used to perform the procedure, and for depicting desired orientational and spatial relationships between them. As opposed to mechanical tracking systems, such as those utilizing sensors (in which the spatial coordinates of the structure being tracked are defined in part by a mechanical process located externally to the body of the patient), the software based tracking system of the present invention defines the spatial coordinates of the structure being tracked with reference only to the software generated image of the patients body, and without reference to external mechanical processes. As such, this system can be said to be "self-referential" rather than "externally-referential". Hereinafter,

therefore, the phrase "self-referential" means "not defined by or involving the use of a mechanical sensor of any sort, be it electrical, optical, magnetic or the like".

According to the teachings of the present invention there is provided an interventional radiological guidance system, including a mechanism for obtaining a plurality of chronologically sequential images of a body; an image identification software module operable to designate at least one self-referential spatial location, defined by a first set of spatial coordinates, within at least one of the chronologically sequential images, the desired self-referential spatial location corresponding to at least one structure in the body; an image tracking software module operable to self-referentially locate a second set of spatial coordinates in a chronologically subsequent image of the body, the second set of spatial coordinates corresponding to the first set of spatial coordinates in a chronologically precedent image of the body, such that the second set of spatial coordinates correspond to the at least one structure; and a graphic aids generator software module operable to generate at least one signal marking a location of the at least one structure in the chronologically sequential images, and operable to describe at least one relationship between a plurality of the at least one structures in the chronologically sequential images. The interventional radiological guidance system may further include a display unit operable to display the signal and the relationship, wherein the signal is displayed as a visual graphic. The interventional radiological guidance system may also further include a sound production unit operable to produce an audible signal corresponding to the relationship. The mechanism for obtaining chronologically sequential images of a body, which may be a human body, may include a three-dimensional ultrasound machine, a two-dimensional ultrasound machine, a computerized tomography scanner, a magnetic resonance imaging scanner, and/or a magnetic resonance therapeutics scanner. The at least one self-referential spatial location may be manually designated, and/or may be designated by an image processing software algorithm, which may be a motion

tracking software algorithm. The structure to which the self-referential spatial location corresponds may include a medical instrument, such as a surgical instrument being used in an interventional radiological procedure, and/or an organic structure, such as a target of a radiologically guided interventional medical procedure and/or a structure which it is desired to avoid in a radiologically guided interventional medical procedure. The relationship described by the graphic aids generator software module may include a desired orientation of one of the structures relative to a second of the structures, a desired minimum distance between one of the structures and a second of the structures, and/or a desired maximum distance between one of the structures and a second of the structures. This relationship may be displayed as a visual graphic.

There is also provided an interventional radiological guidance method, including the steps of obtaining a plurality of chronologically sequential images of a body; designating at least one self-referential spatial location, defined by a first set of self-referential spatial coordinates within at least one of the chronologically sequential images, the desired self-referential spatial location corresponding to at least one structure in the body; self-referentially locating a second set of spatial coordinates in a chronologically subsequent image of the body, the second set of spatial coordinates corresponding to the first set of spatial coordinates in a chronologically precedent image of the body, such that the second set of spatial coordinates correspond to the at least one structure; and generating at least one signal marking a location of the at least one structure in the chronologically sequential images. The method may further include the step of displaying the signal as a visual graphic on a display. The images may be obtained using a three-dimensional ultrasound machine, a two-dimensional ultrasound machine, a computerized tomography scanner, a magnetic resonance imaging scanner, and/or a magnetic resonance therapeutics scanner. The body being imaged may be a human body. The self-referential spatial location may be designated by an image processing software algorithm,

which may be a motion tracking software algorithm, and/or may be manually designated. The structure to which the self-referential spatial location corresponds may be a medical instrument, such as a surgical instrument being used in an interventional radiological procedure, and/or an organic structure, such as a target of a radiologically guided interventional medical procedure, or a structure which it is desired to avoid in a radiologically guided interventional medical procedure. The method may also further include the steps of describing at least one relationship between a plurality of the structures in at least one of the chronologically sequential images, and displaying the relationship as a visual graphic on a display. The relationship may include a desired orientation of one of the structures relative to a second of the structures, a desired minimum distance between one of the structures and a second of the structures, and/or a desired maximum distance between one of the structures and a second of the structures. The method may further include the step of producing an audible signal corresponding to the relationship.

The interventional radiology guidance system (IRGS) is thus based on 3D ultrasound technology, real-time imaging software, and software based tracking algorithms. As opposed to current radiological guidance systems, the interventional radiology guidance system uses image processing software alone, without employing mechanical sensors, to identify and track the surgical instrument.

In the preferred embodiment, the general functioning of the system is as follows:

A standard 3D ultrasound machine is used to continuously acquire 3D ultrasound volumes of the area being imaged. Based on this data, real time 2D ultrasound images are depicted on the display of the 3D ultrasound machine, for viewing by the operator. By extracting data from the 3D volumes, the system is able to provide the operator with an unlimited number of image orientations. For example, the ultrasound data can be viewed from the point of view of the instrument, in relation to a particular plane of the body (coronal,

sagittal, transverse or oblique), or any other chosen angle. As multiple images can be viewed side-by-side simultaneously, 2 orthogonally oriented images can be displayed at the same time, thus facilitating 3D conceptualization, by the operator, of the spatial orientations of the structures being depicted in the 2D images. By "structure" is meant both organic structures (such as the target of an interventional radiological procedure or a structured which it is desired to avoid during an interventional radiological procedure) and non-organic structures such as medical instruments. "Medical instruments" refers to aspiration needles, injection needles, biopsy instruments, scalpels, ablation instruments, biomedical devices such as stents, biomedical prostheses and the like.

When the surgical instrument being used to perform the procedure is introduced into the 3D volume, an image processing software-based tracking system is used to identify the instrument and track its spatial location. In order to improve the visibility of the instrument for the operator, a graphical representation of the instrument is superimposed on the ultrasound image of the instrument displayed on the screen.

The operator then manually designates the target on the image, and marks its center and diameter by using a standard pointing device, such as the electronic calipers incorporated in the imaging system. By "manually" is meant that the target is designated by the operator by hand, rather than automatically by means of a software algorithm. A circle, or other graphical symbol, appears on or around the target in all subsequent ultrasound images, making the target easier to see. The system then tracks the position of the target as the soft tissues, transducer, and instrument move. If the target moves to the extent that it is no longer within the 3D volume, upon relocation the operator is required to re-mark it. If the instrument enters the defined radius of the target, the operator is informed that the instrument is located at or within the target by means of graphic and/or audible signals; for example, the structure's graphical symbol may change color and flash, a beep may be heard, and/or a textual message may

appear on the screen. A hard copy video or print picture documenting that the instrument has reached the target can be generated.

In a similar manner, other structures in the body can be marked and tracked, so as to enable the operator to avoid them during the course of the procedure. In this circumstance, once the operator has designated the areas to be avoided, a graphical symbol appears on or around the structures (making them easier to see), and the system tracks their positions. If the instrument approaches to within a defined distance from the structure (either a default tolerance, or a distance defined by the operator) a warning is provided, for example, the structure's graphical symbol may change color and flash, a beep may be heard, and/or a textual message may appear on the screen.

So as to facilitate optimization of the trajectory of the instrument with regard to the target, a graphical aid is displayed on the ultrasound screen. By reorienting the instrument in accordance with the orientation indicated by the graphic aid, the operator is able to more rapidly and accurately complete the procedure.

In an additional embodiment, 6 DOF physical sensors are mounted on an instrument holder, and can be used to determine the spatial location of the instrument when the instrument is outside of the 3D volume. A graphical representation of the instrument, indicating its location and orientation, can be depicted alongside the ultrasound image, so as to enable the operator to optimize the orientation and trajectory of the instrument before it enters the body and the 3D ultrasound volume.

The interventional radiology guidance system therefore increases the accuracy of interventional procedures by providing a clear image of the instrument in all planes desired by the physician, and by providing graphical (and other) aids which aid the physician in placing the instrument in the target, while avoiding critical structures in the body. When used in conjunction with 6DOF sensors mounted on the surgical instrument, the interventional radiology guidance system can additionally provide information about the instrument's

location and orientation even before it has entered the 3D ultrasound image volume.

With increased accuracy fewer cases will need to be repeated or transferred to other imaging modalities, resulting in lower cost. In addition to the advantages provided by the guidance aspects of the system, being able to verify in real time on intersecting, orthogonal planes that the instrument has successfully entered the target will greatly increase the confidence of the physician doing the procedure.

In summary, this software based tracking system is more reliable than a mechanical sensor based system because:

1. There is no need to perform alignment of the spatial location data with reference coordinate systems.
2. Superimposition of graphic elements on the ultrasound image is 100% precise because the spatial location of the graphic is defined by the voxels of the ultrasound image itself.
3. Appropriate algorithm manipulation can be performed so as to evaluate the resiliency of the surgical instrument within the body in real time.
4. External influences such as magnetic fields or line-of-sight interferences do not effect the system.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is a block diagram of the software components of the IRGS

FIG. 2 is a block diagram of the general flow of control of the IRGS

FIG. 3 is a flow diagram describing the functioning of the algorithm of an instrument tracker

FIG. 4 is a flow diagram describing the functioning of a target, or avoidance target, tracker

FIG. 5 is a diagram illustrating the functioning of a slice generator

FIG. 6 shows the flow of control of a graphic aids generator

FIG. 7a and FIG. 7b show examples of graphic aids generated by an IRGS when oriented in the long axis of a surgical instrument

FIG. 8a and FIG. 8b show examples of graphic aids generated by an IRGS when oriented in the short axis of a surgical instrument.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is an interventional radiology guidance system (IRGS). The IRGS enables ultrasound guided procedures to be performed with increased speed and accuracy by tracking the location of the medical instrument (by which is meant surgical instruments as well as other instruments used in interventional medical procedures, as defined above), the target, and the avoidance targets, and providing the operator with a graphical representation of the instrument's trajectory with relation to the target.

The principles and operation of an interventional radiology guidance system, according to the present invention, may be better understood with reference to the drawings and the accompanying description.

The hardware component of the present invention is a 3D ultrasound machine, including a processing unit, a storage device, and a display unit. In an additional embodiment, 6 DOF physical sensors are mounted on an instrument holder.

The 3D ultrasound machine automatically produces one volume after another as the operator scans the subject. The Kretz (Kretztechnik, Austria) and 3D Ultrasound Inc (Durham, NC, USA) systems are examples of 3D ultrasound machines capable of supplying consecutive 3D volumes, and suitable for use in the IRGS. In the preferred embodiment, the processing unit and storage device are those present in the 3D ultrasound unit. In an alternative embodiment, the

processing unit and storage device are additional components added to the 3D ultrasound unit. A suitable processing unit would include 128MB of RAM and a 166MHz processor. The display unit is that of the 3D ultrasound machine. In a preferred embodiment the system is fully integrated into an existing 3D ultrasound machine. In an alternative embodiment the system is a stand-alone unit, which can be connected to a 3D ultrasound machine.

The software components of the IRGS are located in the processing unit of the 3D ultrasound machine.

Referring now to the drawings, Figure 1 is a block diagram of the software components of an IRGS **12**, and their interrelationship with some hardware components of the system. The software components are: a 3D volume generator **1**, an instrument tracker **5**, a target marker **7**, a target tracker **8**, an avoid marker **4**, an avoid tracker **3**, a slice generator **6**, and a graphic aids generator **9**.

3D Volume Generator **1** provides 3D ultrasound volumes to IRGS **12**. 3D Volume Generator **1** is an external component located in the 3D ultrasound machine. Output from this component is a 3D volume.

Target Marker **7** provides a user interface which enables the user to designate targets. For example, the calipers used to make measurements on an ultrasound screen can be used to indicate the location of a target in a frozen ultrasound image, by marking a circle on the image in one of the views displayed. Target Marker **7** then stores the center point and radius of the designated target. In this way a sphere representing the target in three dimensions is defined.

Avoid marker **4** provides a user interface which enables the user to indicate structures to be avoided (avoidance targets). As with target marking, calipers can be used to indicate the location of structures in a frozen ultrasound image, by marking a circle on the image in one of the views displayed. Avoid marker **4** stores the center point and radius of the structures to be avoided. In this way, a sphere representing the structure to be avoided in three dimensions

is defined. The operator may mark multiple structures for avoidance, with avoid marker **4** being called each time a structure is marked for avoidance.

Instrument tracker **5** is a software algorithm that locates the instrument within the volume provided by 3D Volume Generator **1**. The output provided by this component is a list of x,y, and z coordinates describing the location of the instrument.

Instrument tracker **5**, Avoid marker **4**, and Target Marker **7** are hereinafter collectively referred to as image identification software modules.

The avoid tracker **3** component tracks structures that the operator wishes to avoid touching with the instrument (avoidance targets). It receives as input the position of the instrument, a 3D volume, and the details of the structures to be avoided. It then calculates the distance of the instrument from each of the structures than have been marked for avoidance. If the instrument is "too close" (according to a pre-defined tolerance) a message is sent to Graphics Aids Generator **9** to change the structure's graphical symbol color and cause it to flash. A textual warning message is also displayed. Once the instrument is moved away from the avoidance target, another message is sent to Graphics Aids Generator **9** to return the graphical symbol to its original color, stop the flashing and the remove the textual warning message. The algorithm used to track the structures to be avoided is identical to that used by instrument tracker **5**.

Target tracker **8** is responsible for tracking the target in the 3D volume. The details, center point and radius, of the target are provided by Target Marker **7** and the 3D volume is supplied by 3D Volume Generator **1**. The output provided by this component is a set of coordinates representing the location and shape of the target.

Slice generator **6** generates specific 2D slices from within the 3D volume, according to the angles and orientation designated by the operator during setup of the system.

Graphic Aids Generator **9** is responsible for graphically displaying the instrument, the target, the avoidance targets, and their relationships on each sequential ultrasound image. It receives as input the position and dimensions of the target, the avoidance targets and the instrument, as well as the 2D ultrasound images generated by slice generator **6**. If the distance of the instrument from an avoidance target is "too close" (less than a pre-defined tolerance) then the avoidance targets graphical symbol color is changed (to red for example) and the symbol begins to flash. A textual warning is also displayed. Once the instrument is moved away from the structure, its graphical symbol returns to its original color, stops flashing, and the textual message disappears. When the instrument is inside the target, the target symbol's color changes (to green for example) and the target symbol begins to flash - showing that the user has succeeded in navigating the instrument to the desired location.

If a 6DOF sensor system is used then it is possible for IRGS **12** to receive an instrument location which is outside of the 3D volume. In such a case, graphics aids generator **9** draws the instrument outside of the 2D ultrasound image, in a position representative of the instrument's location with respect to the 3D volume.

A shared memory unit **2** stores 3D volume data generated by 3D Volume Generator **1** of the 3D ultrasound system.

A video card **10** receives output from all of the software components, and a display unit **11**, for displaying input received from video card **10**, are also shown.

A block diagram of the general flow of control of IRGS **12** is depicted in Figure 2. The first step in the iterative process is to access the 3D volume placed in shared memory **2** by 3D volume generator **1** of the 3D ultrasound system. Next a check **13** is performed to see if there are any requests to mark either a target or an avoidance target. If there is a request to mark a target, target marker **7** is called. If there is a request to mark an avoidance target, avoid marker **4** is called. Thereafter, instrument tracker **5** is called, in order to

identify and find the location of the instrument. If there is a marked target **14**, Target Tracker **8** is then called in order to find the target's location in the current 3D volume. Following that, avoid tracker **3** is called for each of the marked avoidance targets (if any) **15**. Then, slice generator **6** is called to produce the 2D slices corresponding to each of the views. Finally, graphic aids generator **9**, which draws the appropriate graphic aids onto the 2D slices, is called. Upon completion, the slices are sent to video card **10** for display on display unit **11**, and the flow is repeated.

Figure 3 is a flow diagram describing the functioning of the algorithm of instrument tracker **5**. The system works in an iterative fashion, identifying and locating the instrument in each consecutive 3D volume it receives. An N depth FIFO queue is used to store sub-volumes. The first step is to read the 3D volume T_n from shared memory **2** . The second step is to define a sub-volume of T_n, T_s, surrounding the instrument. If this is one of the first seven volumes received **16**, the sub-volume is determined by a predefined location **17** (usually the surface of the body) or, in an alternative embodiment, by information received from a 6DOF sensor system. Otherwise the sub-volume is determined **18** by the location of the instrument in volume T_{n-1}. The sub-volume T_s is placed **19** in the FIFO and T_{s-N} is removed **20** from the FIFO (assuming that this is the 9^{th} iteration or more). T_s is then registered **21** to T_{s-1} using a standard registration algorithm such as that described by Barber (Barber D. C., Registration of low resolution medical images. *Phys. Med. Biol.*, 27(3), pp. 87-96, 1992), which is incorporated herein by reference. Following this, the variances are calculated **22** on all of the voxels of all of the sub-volumes in the FIFO and normalized to grey level values. By calculating the variances of each voxel as it changes from frame to frame the instrument is identified by identifying its motion. (Because the instrument is typically difficult to see in ultrasound images, standard edge detection or feature detection alone is often inadequate to identify the instrument, whereas the above described motion

tracking software algorithm is more consistently successful at identifying the instrument.)

Next, edge detection is performed **23** on the sub-volume T_s. A standard edge detection algorithm such as that described by Canny, and which is incorporated herein by reference (J.F. Canny. A computational approach to edge detection. *IEEE Trans. On Pattern Analysis and Machine Intelligence*, 8(6):679-698, November 1986), is used. Using the edges produced by the edge detection algorithm, a 3D Hough Transform **24** (R.O. Duda and P.E. Hart, "Use of the Hough Transform To Detect Lines and Curves in Pictures", *Communications of the ACM*, vol. 15, no. 1, pp. 11-15, 1972), which is incorporated herein by reference, is performed. The result is a list of lines (L_s). If this is the first iteration **25**, then L_s is stored **29** as L_{s-1} and the iteration is completed. If this is not the first iteration **25**, then L_s and L_{s-1} are matched **26** into pairs of lines. These pairs of lines are then used to calculate **27** a flow list, as described by Adiv, incorporated herein by reference (G. Adiv, Determining three-dimensional motion and structure from optical flow generated by several moving objects. *IEEE Trans. on Pattern Analysis and Machine Intelligence*, 7(4):384-401, 1985), the output of the flow list being a list of vectors. On this vector list segmentation is performed **28**, as described by Adiv, 1985 and incorporated herein by reference. The purpose of the segmentation is to identify which of the lines is most likely to represent the instrument. The output of the segmentation is the identified instrument. The x, y, and z points comprising the instrument are then sent **50** to Graphic Aids Generator **9**. The final step is to store **29** L_s as L_{s-1} and then the next iteration begins.

If a 6DOF sensor system, mounted on the instrument (or its holder) and the transducer, is being used, then instrument tracker **5** first calls the 6DOF sensor system to determine if the instrument is within the 3D volume. If it is not within the 3D volume, position data supplied by the sensor to instrument tracker **5** is output directly by instrument tracker **5**, without using the algorithm described above to determine the output of instrument tracker **5**. If the

instrument is within the 3D volume, the above described algorithm is implemented. The advantage of using the 6DOF sensors is that when the instrument is inside the 3D volume, the initial sub-volume (T_s) searched for the instrument is defined by position data received from the sensor and is thus much smaller. This improves the performance of the instrument tracking algorithm.

Figure 4 is a flow diagram describing the functioning of the algorithm for target tracker **8**. The system works in an iterative fashion, locating the target in each consecutive 3D volume it receives. Two 3D volumes are required to find the target. On the first iteration, the previous volume, T_{n-1}, is the frozen volume used by target marker **7**, and prev_target is that supplied by target marker **7**. If it is not the first iteration then T_{n-1} and prev_target are from the previous iteration. T_n, the current volume, is read from shared memory **2**. Then, using the two volumes and the details of the previous target, registration **30** is performed as described by Barber, 1992 and incorporated herein by reference. Registration identifies an area in the volume corresponding to the new target. The target's position, defined as its center point, is calculated **31** and passed to Graphic Aids Generator **9**. Finally, before continuing on to the next iteration, the target is stored **32** as prev_target and T_n is stored **33** as T_{n-1}. The next iteration begins by once again reading a 3D volume from shared memory **2**.

Figure 5 is a diagram illustrating the functioning of slice generator **6**. Each slice is a virtual image frame buffer defined in a world coordinate system. The voxels pierced by the virtual frame are sampled, mapped and displayed in their image coordinate system after the frame is clipped against the volume buffer. In the figure, "P" stands for "point", with P1 being point #1. B is represents the 3D point mapped to 2D. A voxelization algorithm for planar polygons, as described by D. Cohen and A. Kaufman, (Scan conversion algorithms for linear and quadratic objects, in: A. Kaufman, Ed., *Volume Visualization*, IEEE Computer Society Press, Los Alamitos, CA, 1990, pages

280-301) and incorporated herein by reference, is used. The algorithm is basically an extension of the widely known 2D scan-line algorithm (J.D. Foley and A. van Dam and K. Feiner and F. Hughes, in *Computer Graphics Principles and Practice*, Addison-Wesley, 1990.) where at each scan-line the third dimension is also interpolated. Alternatively, the sweeping technique described by Cohen, Kaufman and Kong and incorporated herein by reference, (D. Cohen-Or, A. Kaufman and T.Y. Kong, On the Soundness of Surface Voxelizations, in *Topological Algorithms for Digital Image Processing*, T. Yung Kong and A. Rosenfeld (eds.), North-Holland, Amsterdam, 1995, pages 181-204.) can be used. In this technique a polygon is generated by replicating one discrete line over the other, thus saving most of the computations involved in the discretization process of the plane. The output generated by slice generator **6** is one 2D ultrasound image for each view chosen by the operator. Because the 3D coordinates describing the orientation and tip of the instrument within the 3D volume are known, slice generator **6** is able to calculate the 4 points which define a plane with an orientation within the long or short axes of the instrument. It is thus a feature of the IRGS that the operator can choose to display a 2D ultrasound plane which is consistently oriented within the long or short axes of the instrument, regardless of the motion of the instrument during the procedure. It will be appreciated that multiple other orientations of the 2D imaging plane can be chosen by the operator. In a further embodiment of the current invention, a 3D ultrasound image could be rendered from the 3D volume, for viewing by the operator, instead of individual 2D ultrasound images being rendering by slice generator **6**.

Figure 6 shows the flow of control of the graphic aids generator **9** module. This component works iteratively. For each slice received **34** the following steps are performed. First the 3D representation of the instrument is mapped **35** to a 2D representation and the instrument is drawn **36**. Then, if there is a target **37** the 3D representation of the target is mapped to a 2D representation. If the instrument has hit the target **39** then the target is drawn

40 as a flashing green object. If the target hasn't been hit then the target is drawn 41 without flashing. At this point a loop 42 begins in which each avoid object is processed. For each avoid object, the 3D representation thereof is mapped 43 to a corresponding 2D representation and is drawn in one of two ways. If the instrument hits the avoid object then the avoid object is drawn 44 as a flashing red object. Otherwise the avoid object is drawn normally 46.

Figures 7a, 7b, 8a, and 8b show examples of graphic aids generated by graphic aids generator module 9 to aid the operator in orienting the instrument relative to the target. In figures 7a and 7b the imaging slice has been chosen (by the operator) to constantly be in the long axis of the surgical instrument. As such, the full length of the instrument, including the tip of the instrument, is seen. The circle represents the target, the arrow represents the instrument, and the dotted line represents a projection from the target to the instrument. When the dotted line and the instrument form a straight line, as in figure 7b, the instrument orientation is optimal. In figure 8, the imaging plane is in the short axis of the surgical instrument. The light circle represents the target and the dark circle represents the instrument. Only when the dark circle is located inside the light circle will the instrument penetrate the target if inserted further, as is seen in Figure 8b.

The above description related to image processing of an ultrasound image extracted from a 3D volume of ultrasound image data. It will be understood that by using the same software components (with the exception of slice generator 6, which would not be utilized), the image processing functions of marking and tracking of the instrument, targets and avoidance targets could be performed by IRGS 12 using 2D ultrasound image data instead of 3D data. In this instance, however, the operator would be unable to freely select a desired angle at which to generate the ultrasound image, and could not view more than one image simultaneously. In addition, use of 2D ultrasound data rather than 3D data would preclude a 3D analysis of the relationships between the viewed structures. As such, IRGS 12 would describe only the 2D

relationships between the target, instrument and avoidance targets. Similarly, it will be further understood that additional 2D or 3D digital image data sources (other than ultrasound) - such as CT, MRI, MRT, and the like- can be used to perform the above described image processing functions (marking and tracking of the instrument, targets and avoidance targets, and description of the relationships between them), by using the same software components, provided that the image data source generates chronologically sequential images allowing for the depiction of dynamic events. The phrase "mechanism for obtaining chronologically sequential images" hereinafter refers to all such image data sources.

WHAT IS CLAIMED IS:

1. An interventional radiological guidance system, comprising

a) a mechanism for obtaining a plurality of chronologically sequential images of a body

b) an image identification software module operable to designate at least one self-referential spatial location, defined by a first set of spatial coordinates, within at least one of said chronologically sequential images, said self-referential spatial location corresponding to at least one structure in said body

c) an image tracking software module operable to self-referentially locate a second set of spatial coordinates in a chronologically subsequent image of said body, said second set of spatial coordinates corresponding to said first set of spatial coordinates in a chronologically precedent image of said body, such that said second set of spatial coordinates correspond to said at least one structure, and

d) a graphic aids generator software module operable to generate at least one signal marking a location of said at least one structure in said chronologically sequential images, and operable to describe at least one relationship between a plurality of said at least one structures in said chronologically sequential images.

2. The system of claim 1, wherein said mechanism is selected from the group consisting of three-dimensional ultrasound machines, two-dimensional ultrasound machines, computerized tomography scanners, magnetic resonance imaging scanners, and magnetic resonance therapeutics scanners.

3. The system of claim 1, wherein said body is a human body.

4. The system of claim 1, wherein said at least one self-referential spatial location is designated by an image processing software algorithm.

5. The system of claim 4, wherein said image processing software algorithm is a motion tracking software algorithm.

6. The system of claim 1, wherein said at least one self-referential spatial location is manually designated.

7. The system of claim 1, wherein said structure is selected from the group consisting of medical instruments and organic structures.

8. The system of claim 7, wherein said medical instrument is a surgical instrument being used in an interventional radiological procedure.

9. The system of claim 7, wherein said organic structures are selected from the group consisting of a target of a radiologically guided interventional medical procedure, and a structure which it is desired to avoid in a radiologically guided interventional medical procedure.

10. The system of claim 1, further comprising

e) a display unit operable to display said at least one signal and said at least one relationship, wherein said at least one signal is displayed as a visual graphic.

11. The system of claim 1, wherein said at least one relationship is selected from the group consisting of a desired orientation of one of said at least one structure relative to a second of said at least one structure, a desired minimum distance between one of said at least one structure and a second of said at least one structure, and a desired maximum distance between one of said at least one structure and a second of said at least one structure.

12. The system of claim 11, wherein said relationship is displayed as a visual graphic.

13. The system of claim 1, further comprising

e) a sound production unit operable to produce an audible signal corresponding to said at least one relationship.

14. An interventional radiological guidance method, comprising the steps of

a) obtaining a plurality of chronologically sequential images of a body

b) designating at least one self-referential spatial location, defined by a first set of self-referential spatial coordinates within at least one of said chronologically sequential images, said self-referential spatial location corresponding to at least one structure in said body

c) self-referentially locating a second set of spatial coordinates in a chronologically subsequent image of said body, said second set of spatial coordinates corresponding to said first set of spatial coordinates in a chronologically precedent image of said body, such that said second set of spatial coordinates correspond to said at least one structure, and

d) generating at least one signal marking a location of said at least one structure in said chronologically sequential images.

15. The method of claim 14, wherein said images are obtained using a mechanism selected from the group consisting of three-dimensional ultrasound machines, two-dimensional ultrasound machines, computerized tomography scanners, magnetic resonance imaging scanners, and magnetic resonance therapeutics scanners.

16. The method of claim 14, wherein said body is a human body.

17. The method of claim 14, wherein said at least one self-referential spatial location is designated by an image processing software algorithm.

18. The method of claim 17, wherein said image processing software algorithm is a motion tracking software algorithm.

19. The method of claim 14, wherein said at least one self-referential spatial location is manually designated.

20. The method of claim 14, wherein said structure is selected from the group consisting of medical instruments and organic structures.

21. The method of claim 20, wherein said medical instrument is a surgical instrument being used in an interventional radiological procedure.

22. The method of claim 20, wherein said organic structures are selected from the group consisting of a target of a radiologically guided interventional medical procedure, and a structure which it is desired to avoid in a radiologically guided interventional medical procedure.

23. The method of claim 14, further comprising the step of

e) displaying said at least one signal as a visual graphic on a display.

24. The method of claim 23, further comprising the steps of

f) describing at least one relationship between a plurality of said structures in at least one of said chronologically sequential images, and

g) displaying said relationship as a visual graphic on a display.

25. The method of claim 24, wherein said relationship is selected from the group consisting of a desired orientation of one of said structures relative to a second of said structures, a desired minimum distance between one of said structures and a second of said structures, and a desired maximum distance between one of said structures and a second of said structures.

26. The method of claim 24, further comprising the step of producing an audible signal corresponding to said relationship.

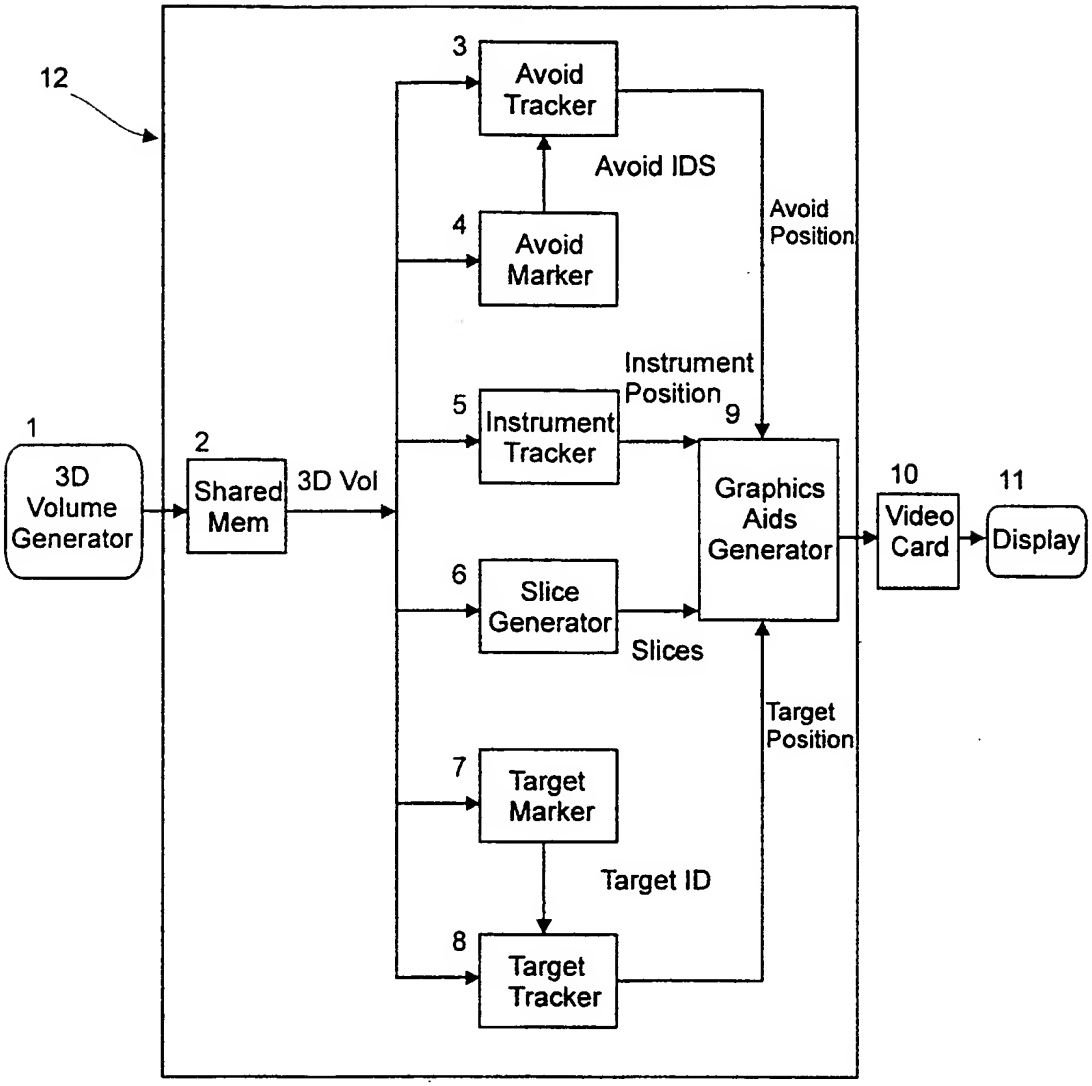
12
3
Avoid Tracker
Avoid IDS
4
Avoid Marker
Avoid Position
Instrument Position
9
1
3D Volume Generator
2
Shared Mem
3D Vol
5
Instrument Tracker
Graphics Aids Generator
10
Video Card
11
Display
6
Slice Generator
Slices
Target Position
7
Target Marker
Target ID
8
Target Tracker

Fig. 1

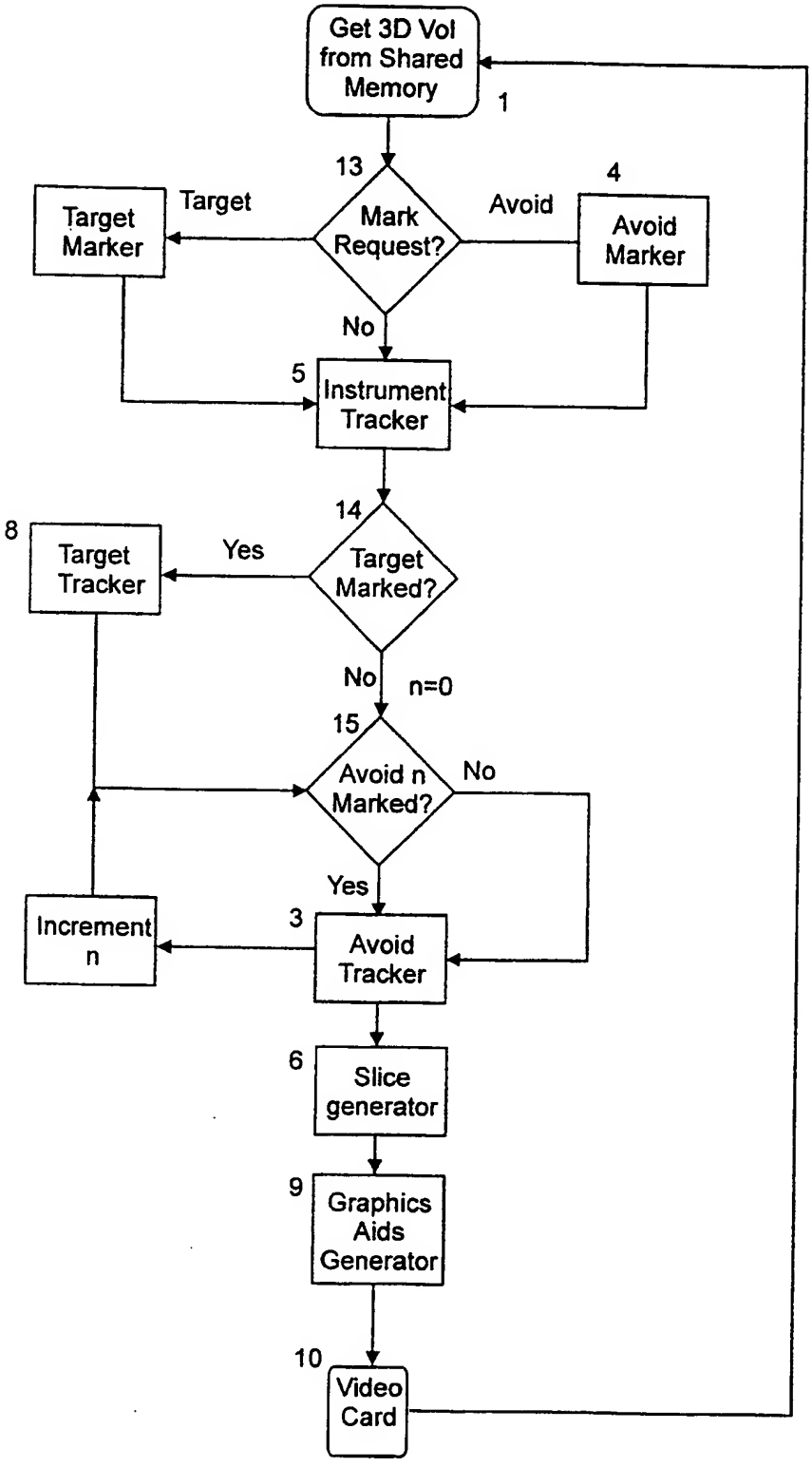

Fig. 2

RECTIFIED SHEET (RULE 91)

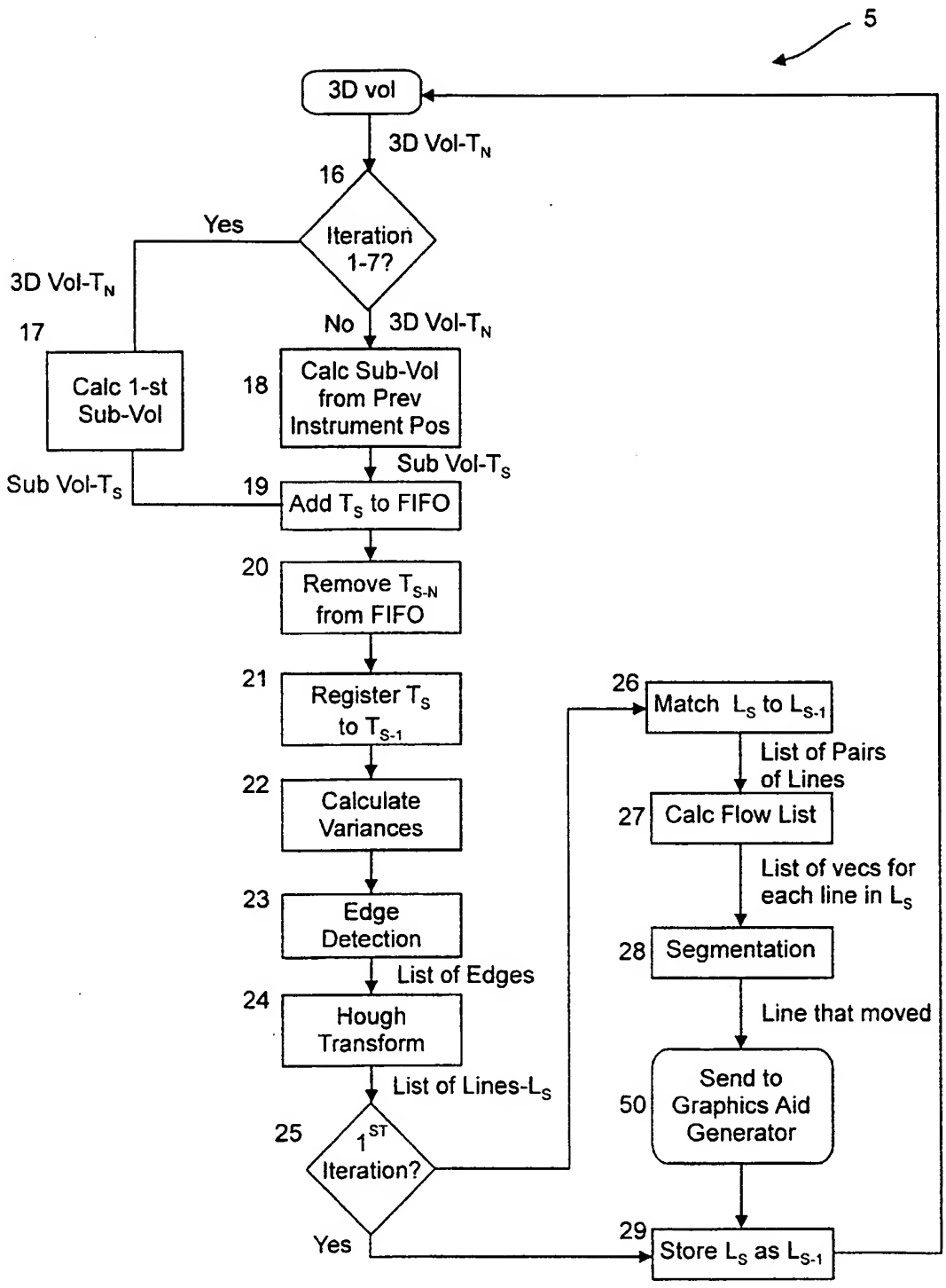
5
3D vol
3D Vol-T_N
16
Iteration 1-7?
Yes
3D Vol-T_N
No
3D Vol-T_N
17
Calc 1-st Sub-Vol
18
Calc Sub-Vol from Prev Instrument Pos
Sub Vol-T_S
Sub Vol-T_S
19
Add T_S to FIFO
20
Remove T_{S-N} from FIFO
21
Register T_S to T_{S-1}
22
Calculate Variances
23
Edge Detection
List of Edges
24
Hough Transform
List of Lines-L_S
25
1ST Iteration?
Yes
26
Match L_S to L_{S-1}
List of Pairs of Lines
27
Calc Flow List
List of vecs for each line in L_S
28
Segmentation
Line that moved
50
Send to Graphics Aid Generator
29
Store L_S as L_{S-1}

Fig. 3

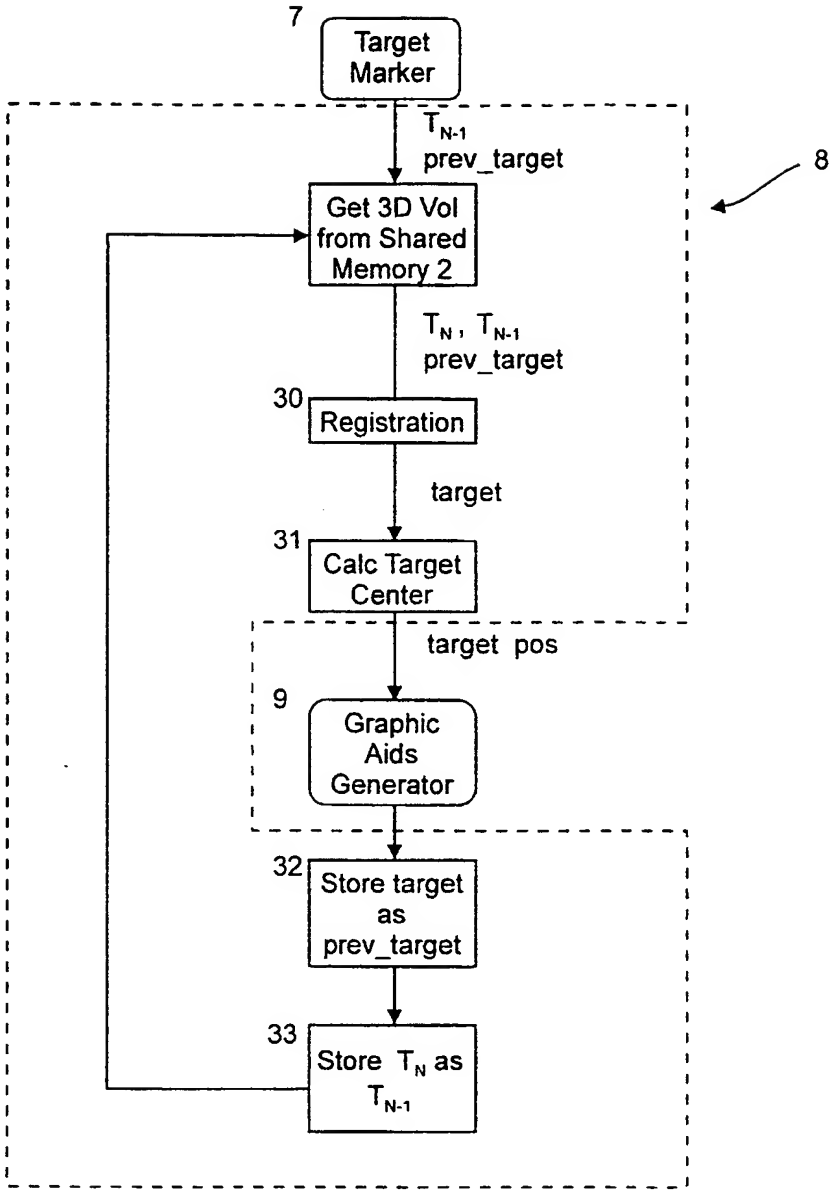
7
Target Marker
T_{N-1} prev_target
8
Get 3D Vol from Shared Memory 2
T_N , T_{N-1} prev_target
30
Registration
target
31
Calc Target Center
target pos
9
Graphic Aids Generator
32
Store target as prev_target
33
Store T_N as T_{N-1}

Fig. 4

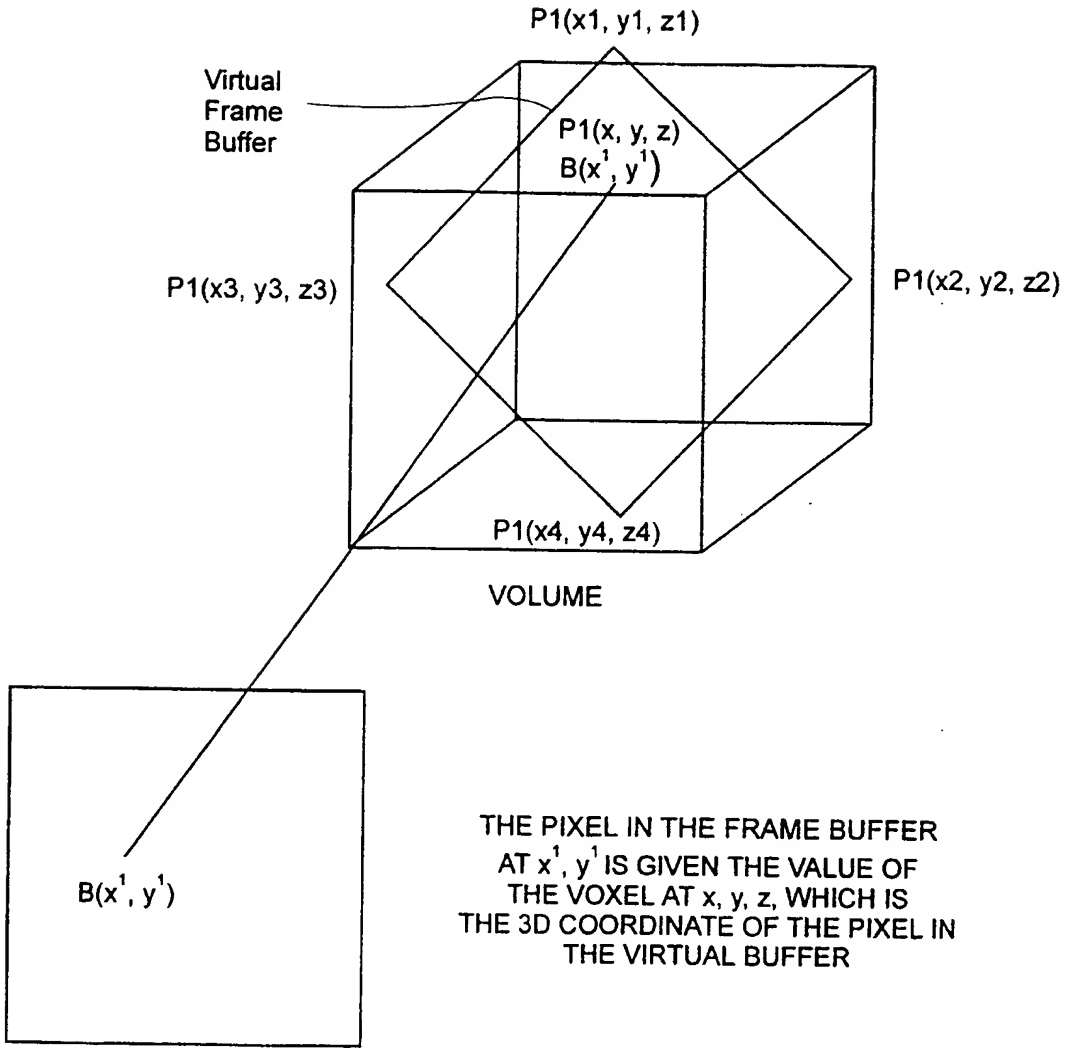
P1(x1, y1, z1)
Virtual
Frame
Buffer
P1(x, y, z)
B(x1, y1)
P1(x3, y3, z3)
P1(x2, y2, z2)
P1(x4, y4, z4)
VOLUME
B(x1, y1)
THE PIXEL IN THE FRAME BUFFER
AT x1, y1 IS GIVEN THE VALUE OF
THE VOXEL AT x, y, z, WHICH IS
THE 3D COORDINATE OF THE PIXEL IN
THE VIRTUAL BUFFER

Fig. 5

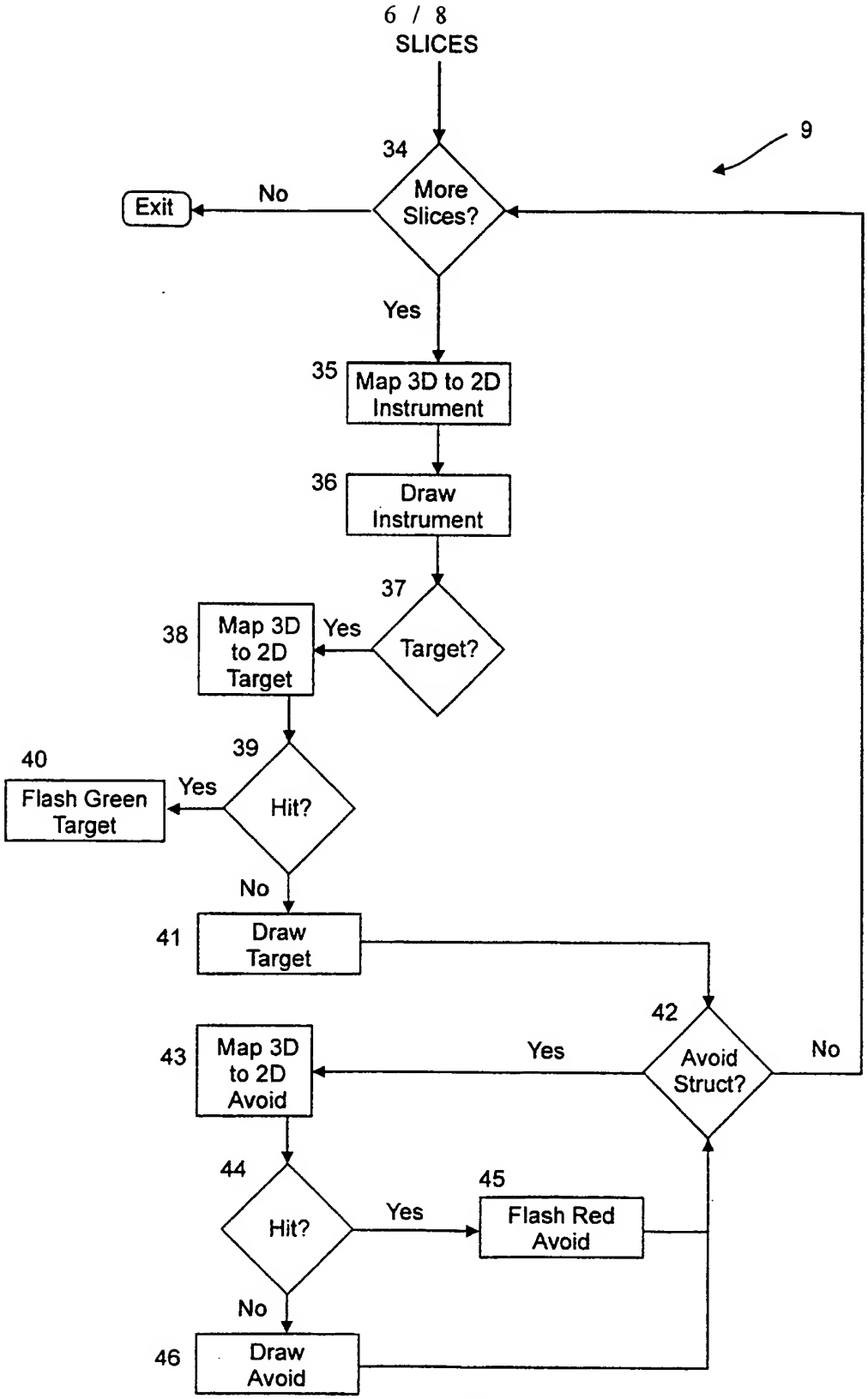
6 / 8
SLICES
9
34
More Slices?
No
Exit
Yes
35
Map 3D to 2D Instrument
36
Draw Instrument
37
Target?
Yes
38
Map 3D to 2D Target
39
Hit?
Yes
40
Flash Green Target
No
41
Draw Target
42
Avoid Struct?
Yes
No
43
Map 3D to 2D Avoid
44
Hit?
Yes
45
Flash Red Avoid
No
46
Draw Avoid

Fig. 6

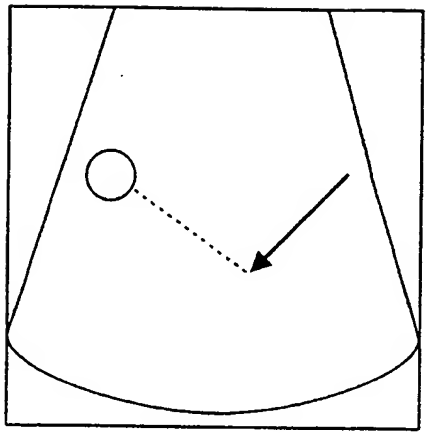

Fig. 7a

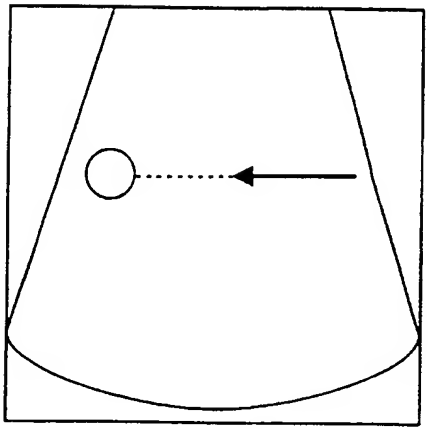

Fig. 7b

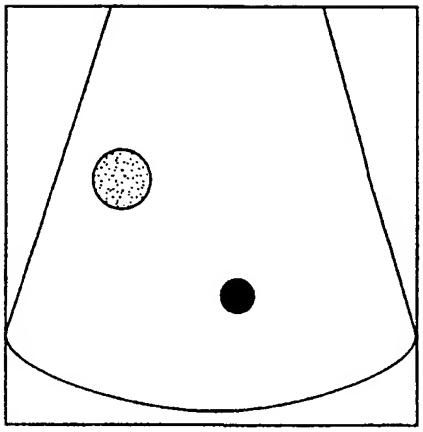

Fig. 8a

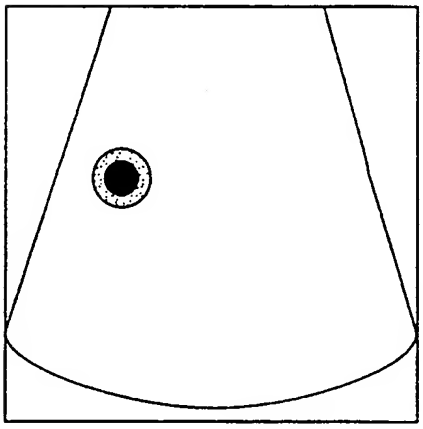

Fig. 8b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19124

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/05
US CL :600/407

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/407

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

600/410, 411, 416, 424, 425, 437; 606/130; 128/920, 922

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 5,765,561 A (CHEN ET AL.) 16 June 1998, see entire document.	1-26
X	US 5,638,819 A (MANWARING et al.) 17 June 1997, see entire document.	1-26
A	US 5,383,454 A (BUCHOLZ) 24 January 1995, see entire document.	1-26
A	US 5,447,154 A (CINQUIN et al.) 05 September 1995, see entire document.	1-26
A	US 5,526,812 A (DUMOULIN et al.) 18 June 1996, see entire document.	1-26
A	US 5,671,739 A (DARROW et al.) 30 September 1997, see entire document.	1-26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
11 FEBRUARY 1999

Date of mailing of the international search report
26 FEB 1999

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